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Subject Environmental Defense comments on  
6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid), CAS#  
88-51-7, and 2-Amino-5-chloro-p-toluenesulfonic Acid  
(C-Amine), CAS# 88-53-9

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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid), CAS# 88-51-7, and 2-Amino-5-chloro-p-toluenesulfonic Acid (C-Amine), CAS# 88-53-9.**

The Color Pigments Manufacturers Association, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a test plan and robust summaries for two chemicals, 6-amino-4-chloro-m-toluenesulfonic acid (2B Acid), and 2-Amino-5-chloro-p-toluenesulfonci Acid (C-Amine). Data for a third chemical, 4-amino-m-toluenesulfonic acid (4B acid) are proposed to address most of the required SIDS elements for the subject chemicals.

Examination of the chemical structures of all three chemicals considered in this submission indicates that the two chemicals of interest have very similar structures and are appropriately considered together. The surrogate from which most of the data in this submission are drawn, 4B acid, shares some structural similarities with the chemicals of interest. The one striking difference between the sponsored chemicals and the surrogate is that the surrogate is not chlorinated. As is very well established, chlorination can very significantly alter the chemical/physical properties, persistence and toxicity of a chemical. An example of how significantly chlorination may alter the properties of the chemicals considered in this document is seen in a comparison of their water solubility. In the robust summaries, the surrogate chemical, 4B acid, is reported to have water solubility of 6 grams/liter (g/l) whereas, in the test plan, one of the sponsored chemicals, C amine, is reported to have a water solubility of only 8.9 mg/l. Given that toxicity, bioaccumulation and many other factors are significantly impacted by water solubility, we do not consider data developed for 4B acid are appropriate to substitute for data required for 2B acid and C amine.

Discussion of available data regarding these chemicals in the test plan is poorly organized and very cursory, providing minimal information. According to the test plan, these chemicals are used as closed system intermediates in the synthesis of pigments. Whether they are exclusively used as closed system intermediates is not mentioned, but should be clearly indicated. It should also be noted that pigments are infrequently highly pure compounds. Thus, information regarding the presence of un-reacted 2B acid and/or C-amine in the pigments for which they are precursors should be provided. If these chemicals are present in appreciable quantities in the finished products, knowledge of the ultimate uses of the respective pigments would be necessary to allow for any assessment of risks they may pose to human health or the environment.

The matrix of required SIDS elements and measured data or estimates provided on page 3 of the test plan claims studies are available to address each of these elements and that no further work is required. This matrix does not, however, indicate which of these elements are addressed by estimated or extrapolated data from the proposed surrogate chemical, 4B Acid. All proposed use of estimates derived from the surrogate should be clearly identified in this matrix. Also, since some measured data are available for the sponsored chemicals, this should be made clear, including where data are available for one or both chemicals.

Discussion of measured data in the test plan is condensed into slightly more than one page. If the test plan is to be a useful document, studies described in the robust summaries should be discussed in some detail in the test plan. The description of studies included under the heading "Health" in the test plan suggests that they were all conducted with C.I. Pigment Red 57. No structure is provided for this chemical and it is not stated how this pigment or these studies may be relevant to the chemicals considered in this submission. The robust summaries indicate that apparently only the reproductive studies were conducted using a chemical that may be C.I. Pigment Red 57. Examination of the structure given for that chemical indicates that it cannot serve as a surrogate for 2B acid or C amine. Thus, the text of the test plan should be revised and the SIDS element for reproductive toxicity cannot be considered to have been fulfilled.

The robust summary also fails to provide an adequate description of a developmental study.

Other comments:

1. It is stated that these chemicals are "largely soluble in water". That does not appear to be the case, as the water solubility of C amine is reported in this test plan to be only 8.9 mg/l.
2. Many of the elements for chemical/physical properties of the subject chemicals are addressed by surrogate data for 4B acid. Given the fact that, as discussed above, 2B acid and C amine are chlorinated and the surrogate is not, these properties may be significantly different than those of the surrogate and should be determined for the respective chemicals.

In summary, this is a very poor submission that should not be considered an acceptable to meet the requirement of the HPV Challenge. As mentioned above, studies described in the robust summaries for reproductive and developmental toxicity appear to have used a chemical that is entirely different from 2B acid and C amine. Thus, these studies and the resulting data are not acceptable as surrogates for 2B acid or C amine.

Thank you for this opportunity to comment.

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